REMARKS

The Office Action dated November 23, 2005 has been carefully reviewed. Claim 1 has been substantially amended in an effort to provide more detail. Claims 3 and 5 have also been amended. Claims 1-3, 5, 7-12, 19, 20 and new claims 23-28 are pending in the application. Reconsideration of the rejection and allowance of Claims 1-3, 5, 7-12, 19, and 20 and new claims 23-28 is respectfully requested on the basis of the following remarks.

NOTE: A petition for extension of time for three months under 37 CFR § 1.136(a) is enclosed herewith and it is respectfully requested that this response be considered timely filed.

As to Claim 1, basis for the terms "target"and "patient" can be found in specification at page 5 at lines 5-6 and 11, respectively; "affinity for each other" is found at the top of page 3 at line 9. Also the limits of Claim 4 have been inserted into amended Claim 1.

The inert into amended Claim 3 can be found on page 9 of the specification at lines 11-12. The insert into amended Claim 11 can be found on page 8 at lines 3-5. Basis for new Claim 23 can be found at page 5, lines 16-19, and page 9 at line 8, as well as in Example 1 and Figs. 2, 3 and 5. New Claim 24 combines previous Claims 5 and 19. Description of the microbubbles can be found, for example, in Example 1, page 10 at lines 21-22 and page 7 at lines 25-30. Basis for new Claims 26 and 27 is found at page 9 of the specification at lines 1-2. Basis for new Claim 29 is found on page 6 at lines 1-6.

Independent Claim 1

Independent claim 1 now also recites that the recognition molecule and the signaling molecule have an affinity for each other allowing binding. Dependent claim 24 (new) specifies both reactive groups and combination of signaling molecule/binding molecule.

35 U.S.C. § 112 ¶1 Enablement Rejections and *In re Wands* Factors

On numbered pages 2-3 of the Office Action, the Examiner has rejected claims 1-5, 7-12, 19, and 20 under 35 U.S.C. § 112 ¶1 for failing to "reasonably provide

enablement [to a person ordinarily skilled in the art] for method for the delivery to a tissue or cell surface of a chemical or biological entity comprising binding a molecule to the cell surface...." The Examiner acknowledges that Applicants' disclosure is enabling for a "two-step delivery of a chemical or biological entity to an isolated vascular tissue comprising of NHS biotin, followed by the attachment of a chemical/biological entity-avidin conjugate..." on numbered page 2 of the Office Action. However, the Examiner also asserts on numbered page 3 of the Office Action that Applicants' disclosure does not reasonably provide enablement to a person skilled in the art for a method for delivery to a tissue or cell surface of a chemical or biological entity.

The Examiner cites to *In re Wands*, 8 USPQ2d 1400 (CA FC 1988) for the factors that are considered in determining whether a disclosure would require undue experimentation and thus not be enabling under 35 U.S.C. § 112 ¶1. Specifically, the *Wands* factors, as cited by the Examiner, include the following: the quantity of experimentation necessary, amount of direction or guidance presented, the presence or absence of working example, nature of the invention, state of the prior art, relative skills of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Independent Claim 1 has now been substantially amended and more clearly defined and recites a method for delivery of a chemical or biological entity to a tissue or cellular surface binding a molecule to the cell surface...attaching the entity to the signaling molecule by means of a recognition molecule, wherein the recognition molecule has an affinity for the signaling molecule. Further limits include "patient" and bonding of the reactive group.

Applicants submit that as to amended claim 1, one of ordinary skill in the art, such as a clinician, may determine a suitable chemical/biological entity, tissue/cellular surface, binding molecule, reactive group, signaling molecule, and recognition molecule depending upon the type of application. Further, as stated on numbered page 8 of the Specification at lines 30-31: "Specificity of delivery [with regard to the present invention] within the body can be engineered to a much greater extent [than previously known methods]." The skilled artisan may refer to the provided three working examples on numbered pages 10-13 of the Specification as well as the Figs., and also the prior art in determining which

pairings will be suitable for a designated application. The disclosure need not describe each and every possible working example that may be used in conjunction with Applicants' invention.

"[A]s part of the quid pro quo of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention." *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234 (Fed. Cir. 2003) (*citing Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). However, "[t]hat is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *Id.* (*citing Wands*, 858 F.2d 731, 736-37 (Fed. Cir 1988) *and Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed.Cir.1997)). Applicants submit that "one skilled in the art" here has a high level of medical expertise. Consistent with the case law, the focus of Applicants' invention is on a method of *specific* delivery of a chemical or biological entity to a targeted surface of a cell and/or tissue.

Further, Applicants state this point on page 8 of the Specification, lines 7-8, "delivery of the molecules and the chemical or biological entities can be by any means known in the art." Numerous examples of the *known prior art* are provided in the Specification. These include, but are not limited to the following as stated on page 8 of the Specification: 1) *direct* delivery of the chemical or biological entity during or immediately following a surgical procedure before the wound is closed using known methods in the prior art; 2) catheter delivery; and, 3) direct injection.

As another example, as explained on page 7, lines 8-10, of the Specification, "[c]ontrast or imaging agents, such as microbubbles, can be locally delivered to aid in diagnostic procedures." Accordingly, one ordinarily skilled in the art would understand that the contrast or imaging agent which is administered to the patient using a standard protocol could contain, at least in part, the microbubbles to aid in the diagnostic procedures. Further, as also stated on numbered page 7, lines 10-15, "[s]ince application of ultrasound causes the microbubbles to rupture, the bubbles can further be used to deliver a drug or other chemical or biological entity to a localized area in the patient; once

the bubbles attach to the target surface, ultrasound can be applied and the drug or other entity [can be] locally released. The energy associated with the application of the ultrasound has been found to actually facilitate the transfer of the drug across membrane surfaces."

1. Breadth of the Claims

The Examiner states that because a broad range of tissues and cell surfaces as targets and a very broad range of biological or chemical entities may be used with the invention, the outcome of using any combination of these would be unpredictable. Applicants respectfully counters the Examiner's contention by referring him to pages 2-3, lines 26-28, of the Specification which states as follows:

> For example, the entity can be chemically modified through the attachment of a recognition molecule to its surface; such attachment can be effected by any means of attachment known in the art or organic chemistry or biochemisty.

The tissue or cell surfaces contain proteins that are modifiable upon binding with the molecule which comprises at least one compatible reactive group. Accordingly, the different mechanisms of action and pharmacokinetics are not of concern so long as the clinician or other individual *selects* a suitable signaling molecule which the tissue or cellular surface can recognize by way of the recognition molecule which is bound thereto; in this manner, we have localized delivery to a target surface. Further, as stated on numbered page 8 of the Specification at lines 30-31: "Specificity of delivery [with regard to the present invention] within the body can be engineered to a much greater extent [than previously known methods]." Applicants believe that one ordinarily skilled in the art would understand that the signaling molecule would have to be selected by a clinician or other individual.

With respect to the discussion of enablement vis-à-vis Applicants' claims (Claim 1, 2-5, 7-12, and 19-20), Applicants' remarks as set forth at page 5 to page 6 are equally applicable here. Accordingly, in view of the foregoing, it is respectfully submitted that Independent Claim 1, Dependent Claims 2-3, 5, 7-12, 19, 20 and new claims 23-28 are enabled under 35 U.S.C. § 112 ¶1.

2. The Nature of the Invention

On numbered page 4 of the Office Action, the Examiner asserts that the nature of the invention is "within the broad genera of gene therapy and gene therapy does not generally enable Applicants' invention due to delivery problems" (*citing Garnett*, Advanced Drug Delivery Reviews, 2001, Vol. 53, 171-216).

First, Applicants respectfully state that *Garnett* is a 2001 publication. However, Applicants claim the benefit under 35 U.S.C. § 119(e) of a U.S. Provisional Application, Serial No. 60/214,865 filed June 28, 2000 on page 1, lines 4-5 of the Specification.

Even if *Garnett* were citable prior art, the Examiner quotes a passage which is directed to delivery problems of macromolecular conjugates on numbered page 4 of the Office Action. Further, the same passage states that there are some barriers in certain cases, but not in all cases .

It is submitted that the Examiner, in citing to *Garnett*, misconstrues the scope of Applicants' invention. The Applicants' disclosure enables the claimed method for delivery of a chemical/biological entity to a certain tissue and/or cellular surface. The person of ordinary skill in the art, such as a clinician, references the prior art to determine what application would be suitable when utilizing the claimed method. Further, as stated on numbered page 8 of the Specification at lines 30-31: "Specificity of delivery [with regard to the present invention] within the body can be engineered to a much greater extent [than previously known methods]." Moreover, the clinician or other person of ordinary skill in the art would choose an application and a method for which the prior art has demonstrated a reasonable likelihood of success. For example, even to the extent that macromolecular drug delivery is a problem, this does not necessarily follow with regard to other forms of drugs (i.e., other than macromolecular) in view of the quoted *Garnett* passage.

3. The State of the Prior Art and the Level of Predictability in the Art/Amount of Experimentation Necessary

On numbered page 5 of the Office Action, the Examiner states that "[t]he issue is whether...a claimed delivery of entities to the tissue or cell surface could have been practiced by a person skilled in the art without undue experimentation...." The Examiner

also asks on the same page of the Office Action, "How would one of skill in the art know that any signaling/recognition molecules pair is effective in delivering of any chemical or biological [entity] to the surface of any tissue in the body?".

The answer to the Examiner's first inquiry is a simple one –it depends upon the *state of the art* that could have been practiced by a skilled artisan at the time the invention was made. Applicants respectfully emphasize that the Examiner may have failed to take into account in this context the teachings of the prior art with regard to suitable signaling/recognition molecule pairs.

Rather, the focus of Applicants' invention concerns the *particular method* used for localized delivery to cellular and/or tissue surfaces. It is the basis of the Specification in combination with the prior art that ultimately teaches the skilled artisan how to use the invention, namely which signaling/recognition molecule would prove successful in the targeted delivery system. Applicants believe that one ordinarily skilled in the art would understand that the prior art would disclose such suitable signaling/recognition molecule pairings.

Accordingly, in view of the foregoing, Independent Claim 1 and Dependent Claims 2-3, 5, 7-12, 19, 20 and new claims 23-28 are enabled under 35 U.S.C. § 112 ¶1.

Peng; *Christian*; *Muzykantov*

On numbered pages 5-6 of the Office Action, the Examiner asserts that the Applicants' claimed method will deliver a pharmaceutical entity to the targeted cells as well as others – i.e., that nonspecific binding of the pharmacological entities may damage normal cells. The Examiner then cites to references which discuss nonspecific binding using the NHS-biotin/avidin system, including *Peng* and *Christian*. The Examiner also cites to *Muzykantov* and states that subsequent avidin attachment to the biotinylated erthrocytes induces lysis of the cells. However, Applicants' invention entails the use of *specific* delivery of a chemical/biological entity and therefore specific binding using a suitable system.

Hoya

With respect to the Hoya reference, the Examiner on numbered page 6 of the Office Action cites this as prior art. The Hoya reference does not appear to be applicable prior art. However, even assuming that Hoya were an applicable prior art reference, the Examiner cites to Hoya as one example of intravascular delivery using endothelial biotinylation and subsequent avidin-FITC binding on numbered page 6 of the Office Action. The Examiner therefore acknowledges on numbered page 6 of the Office Action that specific binding/delivery is possible using such techniques as blocking blood flow in arteries and flushing the arteries with saline prior to the biotin and avidin-FITC binding. This is just one example of specific binding/delivery using various methods and apparatuses known in the prior art which the skilled artisan may utilize.

For the Applicants' disclosure to be enabled under 35 USC 112 paragraph 1, "the specification itself [need not] describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *AK Steel Corp. v. Sollac and Ugine* (*citing Wands*, 858 F.2d 731, 736-37 (Fed. Cir 1988) *and Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed.Cir.1997)).

Hamblett

Further, on numbered page 6 of the Office Action, the Examiner surmises that a "potential barrier [to delivery of the entity in the present invention] is the presence of endogenous biotin in serum, which can block the binding of avidin to the targeted cell/tissue." The Examiner cites the Hamblett reference which was published in 2002 (*Hamblett et al.*, Bioconjugate Chem, 2002, Vol. 13, 588-598).

Moreover, prior art solutions include adding an excess of the targeted agent *or* employing a particulate carrier that would have a great quantity of the targeting entity such as, but not limited to, avidin. These are examples of a few pharmacokinetic solutions that resolve the potential problem as described in *Hamblett*. The skilled artisan may use these or other suitable methods as described in the prior art.

With respect to the discussion of enablement vis-à-vis Applicants' claims (Claims 1, 2-3, 5, 7-12, and 19-20 and new claims 23-28), Applicants' remarks as set forth previously are equally applicable here. Accordingly, in view of the foregoing, Independent Claim 1 and Dependent Claims 2-3, 5, 7-12, 19, and 20 and new claims 23-28 are enabled under 35 U.S.C. § 112 ¶1.

4. The Amount of Direction or Guidance/The Existence of Working Examples

On numbered page 7 of the Office Action, the Examiner states that the Specification only discloses two working examples – an NHS-PEG-biotin binding system to endothelial cells and, the NHS-PEG biotin system to related arteries. The Examiner also states on the same page that the Specification needs to describe examples that address the use of *each relevant* signaling/recognition molecule pair because the present disclosure only provides enough to allow an artisan to use only the two above-mentioned systems.

Applicants respectfully submit that the Examiner may have failed to take into account in this context the teachings of the prior art with regard to suitable signaling/recognition molecule pairs.

The focus of the Applicants' invention is not upon which signaling/recognition molecule would prove successful in the targeted delivery system as disclosed and claimed in the Specification, although *examples* of such combinations are given including the following as recited in Claim 19 and new Claim 24, "biotin/avidin; ligand/receptor; antibody/antigen; primary antibody/secondary antibody; protein A/fc IgG1; and protein c/fc IgG1"; see also page 5 of the Specification at lines 30-34 and page 6 at lines 1-3 (disclosing the same).

With regard to enablement, "the specification [need not] necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234 (Fed. Cir. 2003) (*citing Wands*, 858 F.2d 731, 736-37 (Fed. Cir 1988) *and Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed.Cir.1997)).

Accordingly, in view of the foregoing, Independent Claim 1 and Dependent Claims 2-3, 5, 7-12, 19, and 20 and new claims 23-28 are enabled under 35 U.S.C. § 112 ¶1.

35 U.S.C. § 112 ¶1 Enablement Rejections and N-hydroxy-succinimide

On numbered page 8 of the Office Action, the Examiner has rejected Claims 1, 2, and 7-9 under 35 U.S.C. § 112 ¶1 for failing to comply with the enablement requirement. Applicants agree with the Examiner that the prior art and current state of the art do not teach the feasibility of attaching molecules to cell surfaces using N-hydroxy-succinimide (NHS) as a reactive group. The Applicants also agree with the Examiner's interpretation of the *Miller*, *Muzykantov*, and *Pierce Biotechnology* references which teach that NHS *esters* are used as a reactive group.

Applicants respectfully submit that one of ordinary skill in the art would know that the references to "N-hydroxy-succinimide" at page 5 of the Specification at lines 14-15, Dependent Claim 7 (directly depending from Independent Claim 1), and Claim 9 (indirectly depending from Independent Claim 1) actually entail the use of NHS *ester* with NHS as the leaving group in the organic reaction mechanism. As the Examiner has indicated, the *ester* form of NHS – not NHS *per se* – is described throughout the prior art, including references such as, but not limited to, *Miller*. Accordingly, while Applicants agree with the Examiner that the description of "NHS" may have been clearer, because one of ordinary skill in the art would recognize that what was meant was "NHS ester." Therefore, Claims 1, 2 and 7-9 are enabled under 35 U.S.C. § 112 ¶1.

35 U.S.C. § 102 Anticipation Rejections

Saga *et al.*

On numbered page 10 of the Office Action, the Examiner has rejected Claims 1, 10, 11, 12, and 20 under 35 U.S.C. § 102(b) as being anticipated by Saga *et al.* which, as the Examiner has stated on numbered pages 10-11 of the Office Action, has developed a two-step targeting of lung metastases using biotinylated monoclonal antibodies and delivery of a streptavidin modified entity. Applicants have included the limitations of claim 4 into amended Claim 1. Since Claim 4 is not rejected by Saga et al., including its limitations should negate the rejection based on Saga et al.

Wojda et al.

On numbered page 11 of the Office Action, the Examiner has rejected Claims 1, 4, 5, 7, 9-11, and 19 as being rejected under 35 U.S.C. § 102(a) for being anticipated by Wojda *et al.* As the Examiner has stated on the same page, the Wojda reference uses surface biotinylation and interaction with avidin bioconjugates to facilitate endocytosis into nucleated cells to increase the transfection efficiency of plasmic DNA in cultured cells.

Wojda discloses a method for delivering biotin conjugates to the nucleus of cells. However, unlike Applicants' disclosed and claimed invention, Wojda does not target a specific cell nor does it target a particular tissue. Rather, Wojda describes a *general method* for increasing the endocytosis of existing surface receptors of cells using a biotin/avidin system. "Receptor-adaption should provide a *generic means* for delivering bioconjugates across tissue and species boundaries[.]" (emphasis added).

In contrast, Independent Claim 1 recites a method for delivering a "*chemical or a biological entity* to a tissue or cellular surface...attaching said entity to said signaling molecule by means of a recognition molecule..." (emphasis added). This is a method for direct delivery (not endocytotic delivery) to a targeted cell and/or tissue surface of a chemical or a biological entity.

Moreover, Wojda only discloses using an avidin/biotin system. However, Applicants' invention uses any suitable signaling/recognition system as recited in Claim 1.

Applicants have substantially amended claim 1, providing a variety of important limitations in an attempt to distinguish over Wojda et al. and other cited prior art, and provide a more detailed, specific, clear and concise description of the invention. Applicants respectfully submit that claim 1, as currently amended is not anticipated by Wojda, nor are dependent claims 5, 7, 9, 10, 11 and 19, nor new claims 23-28.

35 U.S.C. § 103 (a) Obviousness Rejections

Saga et al. in view of both Francis et al. and Kaiser et al.

Saga

On numbered page 12 of the Office Action, the Examiner has rejected Claims 1, 2, 8, 10, 11, 12, and 20 under 35 U.S.C. § 103(a) as being unpatentable over Saga et al. in view of both Francis *et al.* and Kaiser *et al.* Claim 4 has not been rejected based on Saga. Applicants have included the limitations of claim 4 into amended claim 1. This should negate the obviousness rejection based on the combination of Saga et al., Francis et al., and Kaiser et al.

Saga et al. in view of both Chinol et al. and Wilbur et al. and Saga et al. and Muzykantor et al.

On numbered page 13 of the Office Action, the Examiner has rejected Claims 1, 10, 11, 12, 19, and 20 under 35 U.S.C. § 103(a) as being unpatentable over Saga et al. in view of both Chinol *et al.* and Wilbur *et al.*; and on numbered page 14 of the Office Action, the Examiner has rejected Claims 1, 3, 10-12 and 20 under 35 U.S.C. §103(a) as being unpatentable over Saga et al. and Muzykantor et al. Claim 4 has not bee rejected by these references. Applicants have included the limitations of claim 4 into amended claim 1. This should negate the obviousness rejection based on the combination of Saga et al. and Muzykantor et al.

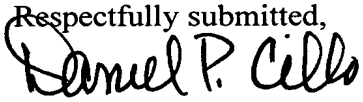
Summary

In view of the foregoing amendments and remarks, Claims 1-3, 5, 7-12, 19, and 20 and new Claims 23-28 are believed to be in allowable form based on the rejections. Additionally, new matter has not been added with respect to any of the claims. Applicants respectfully request reconsideration and allowance of Claim1 1-3, 5, 7-12, 19, 20 and new Claims 23-28. For the Examiner's convenience, the AK Steel Corporation case has been attached.

In the event that any outstanding matters remain in connection with this application, the Examiner is invited to telephone the undersigned at 412-566-5907. Additionally, Applicants appreciate the Examiner's detailed analysis, allowing Applicants to better focus and define the invention.

If the Examiner would like to suggest changes to place this application in better condition for allowance, a telephone call to Applicants' attorney would be appreciated.

Respectfully submitted,



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Briefs and Other Related Documents

United States Court of Appeals,
Federal Circuit.
AK STEEL CORPORATION, Plaintiff-Appellant,
v.
SOLLAC and UGINE, Defendants-Cross Appellants.
Nos. 03-1074, 03-1075, 03-1085, 03-1086.

Sept. 23, 2003.

Owner of patents for manufacturing aluminum-coated stainless steel sued competitors for infringement. The United States District Court for the Southern District of Ohio, 234 F.Supp.2d 711, Susan J. Dlott, J., found one patent invalid and the other not infringed, and appeal was taken. The Court of Appeals, Lourie, Circuit Judge, held that: (1) patent calling for coating of stainless steel with metal "consisting essentially of aluminum" was limited to process in which coating metal contained only up to about 0.5% silicon, and (2) patent for method of coating stainless steel with Type 1 or Type 2 aluminum was invalid for lack of enablement.

Affirmed.

Rader, Circuit Judge, concurred and filed opinion.

West Headnotes

[1] Federal Courts ⇐ 776
170Bk776 Most Cited Cases
District court's grant of motion for summary judgment is reviewed de novo.

[2] Patents ⇐ 226.6
291k226.6 Most Cited Cases

[2] Patents ⇐ 314(5)
291k314(5) Most Cited Cases
Determination of patent infringement requires two-step analysis: (1) court determines scope and meaning of asserted claims as matter of law, and (2) factfinder compares properly construed claims to allegedly infringing device.

[3] Patents ⇐ 314(5)
291k314(5) Most Cited Cases
Whether subject matter of patent claim satisfies the enablement requirement is question of law based on underlying facts. 35 U.S.C.A. § 112¶ 1.

[4] Patents ⇐ 112.5
291k112.5 Most Cited Cases
Evidentiary burden to show facts supporting conclusion of patent invalidity is one of clear and convincing evidence. 35 U.S.C.A. § 282.

[5] Patents ⇐ 101(3)
291k101(3) Most Cited Cases
Patent calling for coating of stainless steel with metal "consisting essentially of aluminum" was limited to process in which coating metal contained only up to about 0.5% silicon; specification stated that any higher levels of silicon would alter basic and novel property of invention.

[6] Patents ⇐ 101(2)
291k101(2) Most Cited Cases
Phrase "consisting essentially of" in patent claim permits inclusion of components not listed in claim, provided that they do not materially affect basic and novel properties of invention.

[7] Patents ⇐ 167(1.1)
291k167(1.1) Most Cited Cases
Statements in patent specification explaining scientific theory by which invention is believed to operate should seldom, if ever, be treated as limitation on claimed invention.

[8] Patents ⇐ 101(2)
291k101(2) Most Cited Cases
Requirement in patent for method of placing aluminum coating on stainless steel, that coating have "up to about 10% silicon," meant that coating had to contain up to and including 10% silicon; phrase was added to clarify initial call for "Type 1 aluminum," which contained about 10% silicon.

[9] Patents ⇐ 165(5)
291k165(5) Most Cited Cases
Other
Independent claims in patent for method of placing aluminum coating on stainless steel, which did not specify composition of coating material, had to at least include coatings having "up to about 10%

silicon," as called for in dependent claims.

[10] Patents ⇦ 99
291k99 Most Cited Cases
Patent for method of coating stainless steel with Type 1 or Type 2 aluminum was invalid for lack of **enablement,** where it failed to teach person of ordinary skill in **art** how to obtain properties claimed for final product using Type 1 aluminum; **specification** taught that use of Type 2 aluminum was required in order to obtained claimed properties. 35 U.S.C.A. § 112¶ 1.

[11] Patents ⇦ 99
291k99 Most Cited Cases
Failure of Patent and Trademark Office to issue enablement rejection does not automatically create especially weighty presumption against invalidation of patent for lack of enablement; rather, whether patent complies with enablement requirement depends upon factually intensive inquiry regarding amount of experimentation required, which is evaluated on case-by-case basis. 35 U.S.C.A. § 112 ¶ 1.

Patents ⇦ 328(2)
291k328(2) Most Cited Cases
4,675,214. Cited as Prior Art.

Patents ⇦ 328(2)
291k328(2) Most Cited Cases
4,800,135. Not Infringed.

Patents ⇦ 328(2)
291k328(2) Most Cited Cases
5,066,549. Invalid in Part.

***1236** David E. Schmit, Frost Brown Todd LLC, of Cincinnati, OH, argued for plaintiff-appellant. With him on the brief was Ann G. Robinson.

Steven P. Weihrouch, Oblon, Spivak, McCelland, Maier, & Neustadt, P.C., of Alexandria, VA, argued for defendants-cross appellants. With him on the brief were Steven E. Lipman, Jean-Paul Lavalleye, Stephen G. Baxter, Michael E. McCabe, Jr., and Clayton W. Thompson, II.

Before LOURIE, CLEVENGER, and RADER, Circuit Judges.

Opinion for the court filed by Circuit Judge LOURIE. Concurring opinion filed by Circuit Judge RADER.

LOURIE, Circuit Judge.

AK Steel Corporation appeals from the decision of the United States District Court for the Southern District of Ohio granting summary judgment that its U.S. Patent 4,800,135 was not infringed by Sollac and Ugine (collectively, "Sollac") and that certain claims of its U.S. Patent 5,066,549 are invalid. *AK Steel Corp. v. Sollac,* 234 F.Supp.2d 711 (S.D.Ohio 2002). Because the court properly construed the patent claims and correctly found no genuine issues of material fact, we affirm.

BACKGROUND

AK Steel owns the '135 and '549 patents, which are directed to hot-dip aluminum-coated stainless steel. The '549 patent issued from an application that was a continuation of the application from which the '135 patent issued. As such, the two patents have different claims but share a common specification. That specification explains that aluminum-coated stainless steel has desirable resistance to corrosion and high-temperature oxidation. ' 135 patent, col. 1, ll. 14-23. Those properties make such steel useful in the manufacture of components for use in automotive exhaust systems and combustion equipment. *Id.* Hot-dip aluminum-coated steel is produced by passing heated steel strips through molten aluminum; however, it is challenging to get the aluminum to adhere or "wet" well onto the steel. *Id.* at col. 2, ll. 21-25. Wetting problems can result in crazing or flaking of the aluminum coating during subsequent bending of the strip. *Id.* at col. 2, ll. 26-27. The inventors of the patents in suit solved the wetting problem by maintaining the steel strip in a hydrogen atmosphere prior to entry into the aluminum coating bath. *Id.* at col. 2, ll. 44-50.

The inventors also discovered that their invention did not work well unless the aluminum is substantially pure, as they stated in their patent application:
Most hot dip aluminum coatings contain about 10% by weight silicon. This coating metal is generally defined in the industry as Type 1. We have discovered this type aluminum coating metal does not wet well with ferritic chromium alloy steel, even when using the hydrogen protective atmosphere. While not being bound by theory, it is believed silicon exceeding 0.5% by weight

decreases the reactivity of the aluminum coating metal needed to react with a ferritic chromium alloy steel substrate. Accordingly, *silicon contents in the coating metal should not exceed about 0.5% by weight.*
***1237** *Commercially pure hot dip aluminum coatings, otherwise known as Type 2 in the industry, are preferred for our invention.* By "pure" aluminum is meant those aluminum coating metals where addition of substantial amounts of alloying elements, such as silicon, are precluded.
Id. at col. 5, ll. 23-40 (emphases added).

The '135 patent, the first of the two patents chronologically, contains one independent claim, which reads as follows:
1. A ferrous base ferritic strip continuously hot dip coated with a coating metal; comprising: the strip including at least about 6% by weight chromium, *the coating metal consisting essentially of aluminum,* the coating layer on said strip being substantially free of uncoated areas and formed without a thick brittle Fe-Al alloy inner layer, said coating layer being tightly adherent to said strip and resistant to crazing or flaking during bending.
Id. at col. 6, l. 62 to col. 7, l. 2 (emphasis added).
The pertinent limitation of that claim, as emphasized above, is that the coating "consist [ ] essentially of aluminum."

The application from which the '549 patent issued was filed as a continuation of the application from which the '135 patent issued. In that continuation application, the inventors sought and obtained broader claims. Rather than require that the coating metal consist essentially of aluminum, the independent claims of the '549 patent require that the coating metal include "aluminum or aluminum alloys" or simply have enhanced wetting characteristics. '549 patent, col. 7, ll. 1-7; col. 8, ll. 5-9. Of the eight claims in the '549 patent, only the odd-numbered ones are at issue in this appeal; they read as follows:
1. A ferrous base ferritic strip continuously hot dip coated with a coating metal, comprising:
the strip including at least about 6% by weight chromium,
the coating metal including aluminum or aluminum alloys,
the coating layer on the strip being substantially free of uncoated areas and formed without a thick brittle Fe-Al alloy inner layer,
the coating layer being tightly adherent to the strip and resistant to crazing or flaking during bending.
3. The strip of claim 1 wherein *the aluminum coating metal contains up to about 10% by weight silicon.*
5. A ferritic steel strip continuously hot dip coated with an aluminum coating metal, comprising:
the strip being stainless steel including at least about 10% by weight chromium,
the coating layer on the strip being substantially free of uncoated areas and formed without a thick brittle Fe-Al alloy inner layer,
the coating layer being tightly adherent to the strip and resistant to crazing or flaking during bending.
7. The strip of claim 5 wherein *the aluminum coating metal contains up to about 10% by weight silicon.*
Id. at col. 6, l. 65 to col. 7, l. 7; col. 8, ll. 1-9, 12-13 (emphases added).

The independent claims 1 and 5 were allowed by the Patent and Trademark Office ("PTO") without amendment or alteration. However, when the dependent claims 3 and 7 were originally filed, rather than reciting that "the aluminum coating contains up to about 10% by weight silicon," they read "the coating metal is Type 1 aluminum." The examiner rejected both claims under 35 U.S.C. § 112, ¶ 2, as being ***1238** indefinite for failing to particularly point out and distinctly claim the subject matter sought to be patented. In particular, the examiner suggested that the phrase "Type 1" should be replaced with the more explicit definition that the applicants had provided in their specification. The applicants complied by replacing the "Type 1" language with the requirement that the silicon content be "up to about 10%," and the PTO then issued the '549 patent.

AK Steel sued Sollac in the district court for infringement of several patents, including the '135 and '549 patents. Sollac manufactures stainless steel that is hot-dipped in a molten mixture including aluminum and 8.0%-8.5% silicon.

The district court judge adopted a special master's construction of the phrase "consisting essentially of aluminum" in the '135 patent claims to permit no more than "about 0.5% silicon" and therefore granted summary judgment of noninfringement. *AK Steel,* 234 F.Supp.2d at 720. The judge also

adopted the special master's thorough construction of claims 1, 3, 5, and 7 of the ' 549 patent as encompassing Type 1 aluminum and his conclusion that the patent did not enable one skilled in the art to practice the invention with Type 1 aluminum, as required by 35 U.S.C. § 112, ¶ 1. *Id.* at 718. The court therefore granted summary judgment of invalidity with respect to those ' 549 patent claims. *Id.* at 719. AK Steel timely appealed and Sollac timely cross-appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

[1] We review a district court's grant of a motion for summary judgment *de novo*. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed.Cir.1998). Summary judgment is appropriate if "there is no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Furthermore, in deciding whether summary judgment is warranted, the court "must view the evidence presented through the prism of the substantive evidentiary burden" that would inhere at trial. *Id.* at 245, 106 S.Ct. 2505.

[2] A determination of patent infringement requires a two-step analysis. "First, the court determines the scope and meaning of the patent claims asserted ... [Second,] the properly construed claims are compared to the allegedly infringing device." *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), that we review *de novo*, *Cybor*, 138 F.3d at 1456. Step two, comparison of a claim to the accused device, requires a determination that every claim limitation or its equivalent is found in the accused device. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). Those determinations are questions of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998).

[3][4] Whether the subject matter of a patent claim satisfies the enablement requirement of 35 U.S.C. § 112, ¶ 1, is a question of law based on underlying facts, *In re Wands*, 858 F.2d 731, 735 (Fed.Cir.1988), and, because a patent is presumed to be valid, 35 U.S.C. § 282 (2000), the evidentiary burden to show facts supporting ***1239** a conclusion of invalidity is one of clear and convincing evidence, *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1355 (Fed.Cir.1999).

On appeal, AK Steel argues that the court erred by interpreting the ' 135 patent claims too narrowly and the '549 patent claims too broadly. It contends that the claims of both patents should be construed to cover coating baths containing up to, but not including, 10% silicon. Under that claim construction, according to AK Steel, there are genuine issues of material fact relating to infringement of the '135 patent claims and enablement of the '549 patent claims.

Sollac responds that the court correctly construed both patents' claims and properly found no genuine issue of material fact as to noninfringement of the ' 135 patent claims and lack of enablement of the involved '549 patent claims. Sollac also cross-appeals, arguing that the court abused its discretion in denying it summary judgment of invalidity of the same '549 patent claims on the grounds of lack of written description and anticipation by AK Steel's earlier U.S. Patent 4,675,214. The district court adopted the special master's recommendation to deny summary judgment of invalidity for lack of written description and not to decide the anticipation issue.

A. *The '135 Patent*

[5] AK Steel argues that the district court erred in interpreting the phrase "consisting essentially of aluminum" in the '135 patent claims to permit only up to about 0.5% silicon. Rather, according to AK Steel, the correct interpretation permits silicon in an amount up to but not including 10%, as the intrinsic evidence shows that about 10% silicon materially changes the novel characteristics of the invention. AK Steel contends that the court read the specification's statement that "silicon should not exceed about 0.5%" out of context. That statement, which advanced a theory that the applicants expressly stated was not binding on them, relates to reactivity, according to AK Steel, not to the critical

characteristic of the claimed invention--good wetting.

Sollac responds that the specification clearly states that the invention is to be used with pure or nearly pure aluminum and should not be used with Type 1 aluminum. Sollac further contends that the prosecution history also contains statements expressing that view. Finally, Sollac contends that, given the choice between a broader and narrower construction, and the enablement concerns raised by the broader one, the narrower one should prevail.

[6] We agree with the district court's construction of the disputed claim language. The phrase "consisting essentially of" in a patent claim represents a middle ground between the open-ended term "comprising" and the closed-ended phrase "consisting of." In view of the ambiguous nature of the phrase, it has long been understood to permit inclusion of components not listed in the claim, provided that they do not "materially affect the basic and novel properties of the invention." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed.Cir.1998); *In re Janakirama-Rao,* 50 C.C.P.A. 1312, 317 F.2d 951, 954 (CCPA 1963). Thus, the claim construction issue presented by the '135 patent in this case is whether an amount of silicon in excess of 0.5% in the aluminum coating materially affects the basic and novel properties of the invention.

To determine those properties, we need look no further than the patent **specification**. The **specification** clearly states that good wetting is the goal of the invention as ***1240** well as what distinguishes it from the **prior art**. *See* '135 patent, col. 2, ll. 66-68 ("It is a principal object of this invention to form hot dip aluminum coated ferritic chromium alloy steels having enhanced wetting by the coating metal."). The **specification** also clearly states that Type 1 aluminum containing "about 10%" silicon contains too much silicon and does not achieve that goal, *id.* at col. 5, ll. 23-29, whereas Type 2 or nearly pure aluminum does and is therefore preferred, *id.* at col. 5, ll. 35-40. Furthermore, the specification draws a precise line between those two materials, demarking the exact percentage of silicon that the inventors considered to be too much silicon, when it states, "[s]ilicon contents in the coating metal should not exceed about 0.5% by weight." *Id.* at col. 5, ll. 33-34. On the basis of that statement, we conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention, and that the claims of the '135 patent must therefore be interpreted to permit no more than 0.5% silicon by weight in the aluminum coating.

[7] AK Steel's attempt to distance itself from the clear limiting statements in its specification is unavailing. While it is true that statements in a specification explaining a scientific theory by which an invention is believed to operate should seldom, if ever, be treated as a limitation on a claimed invention, *e.g., Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1570 (Fed.Cir.1983), the district court did not do so here. There is a distinction between an inventors' theory as to the reason for a limitation and the meaning of that limitation. By its very terms, the specification here expresses the inventors' desire not to be bound by the reactivity theory they present to explain why aluminum with more silicon does not wet well. *See* '135 patent, col. 5, ll. 29-34 ("While not being bound by theory...."). However, no such disclaimer attaches to the following conclusion that silicon should not exceed 0.5%. That conclusion is not a theory; it is an expression speaking to the conditions under which the invention will or will not operate properly. As such, AK Steel cannot escape its impact upon the meaning of the claim phrase "consisting essentially of aluminum."

Nor are we persuaded by AK Steel's arguments that the determination whether more than 0.5% silicon materially alters the basic and novel properties of the invention is a question of fact that must be answered by the jury. While "consisting essentially of" language in a patent claim can at times blur the distinction between the separate steps in an infringement analysis (claim construction and comparison of the construed claim to the accused device or method), the distinction is clear enough in this case. AK Steel cites *PPG Industries* to support its position that that determination is a factual one for the jury. Indeed, we held in that case that "[t]he court properly left it to the jury to determine whether the amounts of iron sulfide in [the accused] SMG glass have a material effect on the basic and novel characteristics of the glass." *Id.* However, we so held there because, as we stated in the immediately preceding sentence, "The district judge properly recognized that the patent is silent about

iron sulfide and about what constitutes a material effect on the properties of the glass." *Id.* In this case, quite differently, the specification is far from silent regarding silicon and its material effect on the properties of the aluminum coating bath and the resultant coated steel; as explained above, the specification directly speaks to and conclusively answers that question. Therefore, it is as a matter of claim construction that we hold that the claims of the '135 patent do not encompass steel coated with aluminum containing ***1241** more than about 0.5% silicon. The only factual issue that remains is the simple one whether the claims, so interpreted, read on Sollac's steel strips coated with aluminum containing 8.0% silicon. They do not, and no reasonable juror could conclude otherwise, given the fact that 8.0% is far in excess of 0.5%. We therefore affirm the court's grant of summary judgment of noninfringement of the '135 patent.

B. *The '549 Patent*

We next turn to the '549 patent and the question whether the court correctly granted summary judgment that the contested claims of that patent are not enabled. Because a patent specification must enable the full scope of a claimed invention, *In re Wright,* 999 F.2d 1557, 1561 (Fed.Cir.1993), an enablement inquiry typically begins with a construction of the claims, *see* MPEP § 2164.08 (8th ed., rev.1-2003) ("All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether the substantial scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims.").

1. *Claim Construction*

[8] AK Steel argues that the district court's construction of the '549 patent claims as including Type 1 aluminum is contrary to (1) the ordinary meaning of "up to" as not including the 10% endpoint; (2) the claims' recitation that the coating must wet well; (3) the specification's clear disclaimer of Type 1 aluminum; and (4) the axiom that claims should be interpreted to preserve their validity. According to AK Steel, the court mistakenly assumed that the applicants did not narrow the claims when they replaced the words "Type 1 aluminum" with "up to about 10%" silicon, when in fact they did so to surrender that subject matter.

Sollac responds that AK Steel's dictionary definition of "up to" is nonsensical where a numerical limit follows that phrase. In such a case, according to Sollac, the limit is included (*e.g.*, counting up to ten stops at ten, not nine). Sollac also contends that the amendment replacing "Type 1" with "up to about 10%" was presented as an improvement in clarity, not as an exclusion of subject matter. Moreover, the amendment affected only the dependent claims, not the independent claims, which were submitted with an explanation that they encompass any type of aluminum.

We agree with Sollac as to the meaning of the '549 patent claims. We begin with the dependent claims 3 and 7. Those claims state that the silicon content of the aluminum coating is "up to about 10%." '549 patent, col. 7, l. 11; col. 8, l. 13. We hold that those claims do indeed extend up to, and include, 10% silicon in the aluminum coating, *i.e.*, Type 1 aluminum coatings.

First, we conclude that the ordinary meaning of the phrase "up to about 10%" includes the "about 10%" endpoint. As pointed out by AK Steel, when an object of the preposition "up to" is nonnumeric, the most natural meaning is to exclude the object (*e.g.*, painting the wall up to the door). On the other hand, as pointed out by Sollac, when the object is a numerical limit, the normal meaning is to include that upper numerical limit (*e.g.*, counting up to ten, seating capacity for up to seven passengers). Because we have here a numerical limit--"about 10%"--the ordinary meaning is that that endpoint is included.

Moreover, the prosecution history shows that the phrase was introduced into the claims with the intention and effect of covering the endpoint. Claims 3 and 7 originally ***1242** recited "Type 1 aluminum," and it is clear that the inventors intended to obtain claims covering Type 1 aluminum. During prosecution, however, AK Steel amended those claims to remove reference to Type 1 aluminum and to put in its place language expressing the "up to about 10% silicon" language. There was no indication that the amendment was made to relinquish claim scope; rather it was made in response to the examiner's request to replace

language that he found vague with language that he felt "more specifically defined" the same material. Under those circumstances, the amendment clarified the claims without changing their scope. On the basis of that prosecution history alone, claims 3 and 7 must be interpreted to encompass Type 1 aluminum. In addition, because the specification defines Type 1 aluminum as "contain[ing] about 10% by weight silicon," *id.* at col. 5, ll. 25-28, *i.e.*, the endpoint recited in the amended and issued claims, it follows that the claims encompass, rather than exclude, both an aluminum coating having about 10% silicon and a Type 1 aluminum coating.

[9] Turning next to the independent claims, we begin their interpretation by analyzing their ordinary meaning. According to their plain language, independent claim 1 permits the coating metal to include any "aluminum or aluminum alloy," *id.* at col. 7, ll. 1-2, while independent claim 5 does not contain any express limitation regarding the composition of the coating metal, other than that it be "an aluminum coating metal," *id.* at col. 8, l. 2. The ordinary meaning of those phrases in claims 1 and 5, then, is that they encompass a metal coating mixture of aluminum, including perhaps a significant amount of silicon. We need not determine the upper limit, if any, of silicon that the claim language permits, but the claims must cover up to at least 10% silicon, as the parties do not dispute that a mixture of about 10% silicon and approximately 90% aluminum is an "aluminum alloy" and "an aluminum ... metal." *Id.* at col. 7, ll. 1-2; col. 8, l. 2.

Moreover, and most importantly, claims 1 and 5 must also encompass aluminum with up to about 10% silicon, *i.e.*, Type 1 silicon, because claims 3 and 7, which depend from claims 1 and 5, respectively, expressly recite "up to about 10% silicon." Under the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend. *See RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1264 (Fed.Cir.2003) (stating that an independent claim is usually accorded a scope greater than its dependent claims); *see also* 35 U.S.C. § 112, ¶ 4 (2000) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."). That presumption is applicable in this case and has not been rebutted. If the dependent claims expressly recite "up to about 10%" silicon, then the independent claims, which must be at least as broad as the claims that depend from them, must include aluminum coatings with "up to about 10%" silicon. Independent claims 1 and 5 therefore also cover at least steel strips hot-dip coated with aluminum containing about 10% silicon, *i.e.*, Type 1 aluminum.

AK Steel's remaining arguments concerning the interpretation of the claims are unpersuasive. First, AK Steel points to language in the independent claims describing the functional qualities of the coating layer, *i.e.*, "being substantially free of uncoated areas," "formed without a thick brittle Fe-Al alloy inner layer," and "being tightly adherent to the strip and ***1243** resistant to crazing or flaking during bending." '549 patent, col. 7, ll. 3-7; col. 8, ll. 5-9. AK Steel would like us to interpret those limitations as requiring that the coating metal contain less than about 10% silicon. That we cannot do, because, as indicated above, we have concluded that the claims include coatings with 10% silicon as well as possessing the recited properties. While the specification does state that use of a Type 2 but not a Type 1 aluminum coating results in the four properties recited in the claims, thereby implying that the percentage of silicon in the aluminum coating must be quite low in order for the resulting coating to have the claimed wetting characteristics, that implication does not override the clear meaning of the claims as both the district court and this court have construed them. Those claim limitations speak clearly as including 10% silicon, and that is how we must interpret them.

AK Steel's contention that a narrower construction of the '549 patent claims is in order under the axiom that claims should be interpreted to preserve their validity when possible is also unpersuasive. That axiom is a qualified one, dependent upon the likelihood that a validity-preserving interpretation would be a permissible one. In this case, the interpretation advocated by AK Steel, while possibly avoiding validity pitfalls, cannot be a correct interpretation, for it is counter to the ordinary meaning of the claims as well as to the prosecution history.

We recognize that we have interpreted differently two similar claims supported by the same specification. We are holding that one set of claims is limited to 0.5% silicon; the other, up to and including about 10%. Such a situation may be regarded as unusual. However, that is a necessary consequence of the clear statements in the specification, as applied to the '135 patent claims, and the fact of claim dependency and the prosecution history, as applied to the ' 549 patent. The '135 patent claims also contain the narrowing term "consisting essentially of," which is not in the '549 patent claims. Thus, our differing constructions of the two patents' claims is compelled by all of the relevant facts.

2. *Enablement*

Given our construction of the '549 patent claims, we turn to the question whether the district court properly determined that those claims have not been enabled.

AK Steel principally argues that the court's enablement holding was premised on a faulty claim construction, a point we have already rejected. AK Steel further contends that Sollac failed to submit any evidence--let alone clear and convincing evidence--of undue experimentation, and that AK Steel is entitled to the presumption of validity, which it contends is especially weighty. Finally, AK Steel contends that the patent discloses several embodiments within the properly construed claim range, and that the patent specification need not teach the full claimed range in order for the claims to be enabled.

Sollac responds that under the court's construction of the '549 patent claims, they are not enabled in their full scope. As evidence of nonenablement, Sollac points to the statements in the specification itself, as well as AK Steel's own documents and testimony from its personnel reflecting their inability to use 9% silicon Type 1 aluminum effectively.

[10] We agree with the district court that the claims as construed have not been **enabled.** The **enablement** requirement is set forth in the first paragraph of section 112 of title 35, which provides in pertinent part that the **specification** shall describe "the manner and process of making and ***1244** using [the invention], in such clear and concise, and exact terms as to **enable** any person skilled in the **art** to which it pertains, or with which it is most nearly connected, to make and use [the invention]." 35 U.S.C. § 112, ¶ 1 (2000). The **enablement** requirement is satisfied when one skilled in the **art**, after reading the **specification**, could practice the claimed invention without undue experimentation. *Wands,* 858 F.2d at 736-37.

As we have stated, all of the contested '549 patent claims read on steel strips containing either a Type 1 or a Type 2 aluminum coating. Furthermore, the claims require that the coating wet well. The specification undoubtedly enables the invention in the latter form, as it clearly describes how to make and use such strips with Type 2 aluminum, and there is no question that the resulting strips are well-wetted. However, as part of the *quid pro quo* of the patent bargain, the applicant's **specification** must **enable** one of ordinary skill in the **art** to practice the full scope of the claimed invention. *Wright,* 999 F.2d at 1561. That is not to say that the **specification** itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the **prior art** and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the **art**. *See Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1366 (Fed.Cir.1997) ("[A] **specification** need not disclose what is well known in the **art**."); *see also Wands,* 858 F.2d at 736-37 ("**Enablement** is not precluded by some experimentation, such as routine screening."). But it does mean that, when a range is claimed, there must be reasonable **enablement** of the scope of the range. The question more precisely here is whether, with AK Steel's patent **specification** as an initial guide, the hypothetical skilled artisan's knowledge of the surrounding **art** and ability to modestly experiment would have been sufficient to **enable** him to make and use a steel strip containing a Type 1 aluminum coating, with the claimed wetting attributes, at the time of the '549 patent's effective filing date in 1986.

We conclude that the **specification** is inadequate as a matter of law in that regard primarily because it expressly teaches against it. Worse than being silent as to that aspect of the invention, the **specification**

clearly and strongly warns that such an embodiment would not wet well. In particular, the **specification** warns that silicon **content** above 0.5% in the aluminum coating causes coating problems. Such a statement discourages experimentation with coatings having more than 0.5% silicon, undue or otherwise. It tells the public that higher amounts of silicon will not work. Nothing further need be said about the matter.

Moreover, we disagree with AK Steel's contention that Sollac failed to submit evidence that undue experimentation would be required to enable practice of the claims. Sollac presented documentary and testimonial evidence from AK Steel that despite its desire to utilize a Type 1 aluminum coating, it was unable to do so at the time of the effective filing date. *AK Steel,* 234 F.Supp.2d at 782-83. Furthermore, as explained above, the specification's teaching is itself evidence that at least a significant amount of experimentation would have been necessary to practice the claimed invention utilizing Type 1 aluminum. In summary, given the specification's teaching away from the subject matter that was eventually claimed and AK Steel's own failures to make and use the later claimed invention at the time of the application, the district court correctly concluded that there was no genuine issue of ***1245** material fact relating to undue experimentation as it relates to enablement.

[11] Finally, we dispel the notion that the failure of the PTO to issue an enablement rejection automatically creates an "especially weighty presumption" of compliance with 35 U.S.C. § 112. AK Steel cites language in *Brooktree Corp. v. Advanced Micro Devices, Inc.,* 977 F.2d 1555, 1574-75 (Fed.Cir.1993), to that effect. However, whether a patent complies with the enablement requirement depends upon a factually intensive inquiry regarding the amount of experimentation required, *see Wands,* 858 F.2d at 737, an issue to be evaluated on a case-by-case basis. Indeed, the presumption is far from determinative, and we have on occasion invalidated patent claims as not having been enabled, despite the PTO's having allowed those claims. *E.g., Genentech,* 108 F.3d at 1368. This is another such case. The specification here itself plainly tells us that use of aluminum up to about 10% silicon is not enabled.

To conclude, the specification does not enable a significant portion of the subject matter encompassed by the contested claims of the '549 patent, as properly construed. Accordingly, we affirm the district court's judgment of invalidity of those claims on the ground of noncompliance with 35 U.S.C. § 112, ¶ 1.

3. *Cross-Appeal*

Finally, because we affirm the court's judgment that the contested claims of the '549 patent are invalid, we need not reach Sollac's cross-appealed issues, which are alternative grounds for reaching the same judgment.

CONCLUSION

Because the court correctly construed the claims of the '135 and '549 patents, and there are no genuine issues of material fact disentitling AK Steel to summary judgments of noninfringement and invalidity, respectively, as a matter of law, we

AFFIRM.

RADER, Circuit Judge, concurring.

While I endorse the results and reasoning of the majority, I write separately to present an alternative reason for concluding that contested claims 1, 3, 5, and 7 of the '549 patent are invalid. This court sustained the district court's determination that those claims were invalid for lack of an **enabling** disclosure. The district court declined to reach a point raised by the special master, namely that **prior art** anticipated those claims. The record suggests that the special master was correct.

In this case, the **prior art** is the '549 patent's grandparent U.S. Patent No. 4,675,214 (the '214 patent). The '549 patent is the third in a group of related patents with identical disclosures. The '214 patent was the first in that series. The '214 patent as filed disclosed that "silicon contents in the coating metal should not exceed about 0.5% by weight." '214 patent, col. 5, ll. 30-31. The later '549 patent recites in the contested claims a coating metal containing "aluminum," "aluminum alloys," or "up to about 10% by weight silicon." Thus, the later '549 patent added new matter to the original disclosure. Specifically, the later patent claimed much higher concentrations of silicon. Because the specification of the '214 patent as filed contains no

support for this new matter, the applicant cannot claim priority back to the filing date of the earlier application that matured into the '214 patent. [FN1]

FN1. For the same reason, the contested claims do not benefit from the filing date of the intermediate '135 patent.

***1246** Without a valid priority claim, the '214 patent is prior art. The '214 patent issued on June 23, 1987, over one year before the '549 patent's filing date of November 22, 1988. The '549 patent' s claims encompass subject matter disclosed in the earlier '214 patent. As the special master acknowledged, the '214 patent anticipates the contested claims.

Thus, when an applicant files continuation applications, a patent issuing from an earlier application may anticipate claims containing new matter under 35 U.S.C. § 132. When the earlier application lacks any support in the written description for the new subject matter, the new matter cannot claim priority back to the original filing. In that case, a patent issuing from the earlier application may become anticipatory prior art, as occurred here.

344 F.3d 1234, 68 U.S.P.Q.2d 1280

Briefs and Other Related Documents (Back to top)

. 2003 WL 24027214 (Appellate Brief) Reply Brief of Defendants-Cross Appellants Sollac and Ugine (May. 02, 2003)Original Image of this Document (PDF)

. 2003 WL 24027213 (Appellate Brief) Corrected Reply Brief for Plaintiff-Appellant and Response to Conditional Cross-Appeal (Apr. 08, 2003)Original Image of this Document (PDF)

. 2003 WL 24027212 (Appellate Brief) Brief of Defendants-Appellees Sollac and Ugine (Feb. 24, 2003)Original Image of this Document (PDF)

. 2003 WL 24027211 (Appellate Brief) Brief for Plaintiff-Appellant (Jan. 13, 2003)Original Image of this Document with Appendix (PDF)

. 03-1086 (Docket) (Nov. 15, 2002)

. 03-1075 (Docket) (Oct. 28, 2002)

. 03-1074 (Docket) (Oct. 28, 2002)

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